U.S. Progress in Applying Biotechnology to Defense

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What is “Biotech”?

- Very diverse sector in terms of
  - information generated and used
  - techniques applied
  - products produced
  - production processes involved
  - firms / institutions responsible
- More than high-tech therapeutics and vaccines

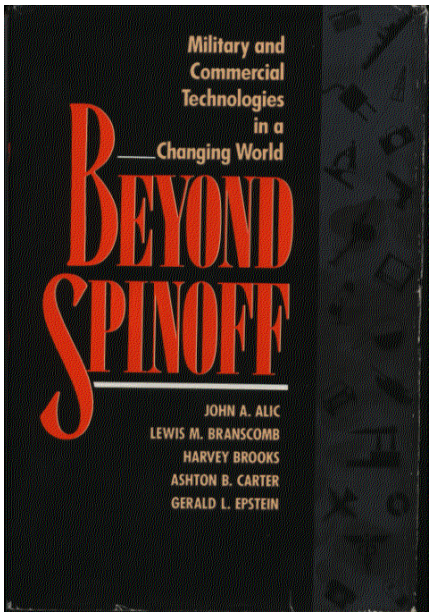
What is “Defense”?

- Department of Defense applications
  - defense against biological attack (biodefense)
  - other military medical applications
  - other military applications
- Homeland Security applications
  - civilian federal agencies
  - state and local government
  - private sector

What is “Applying”?

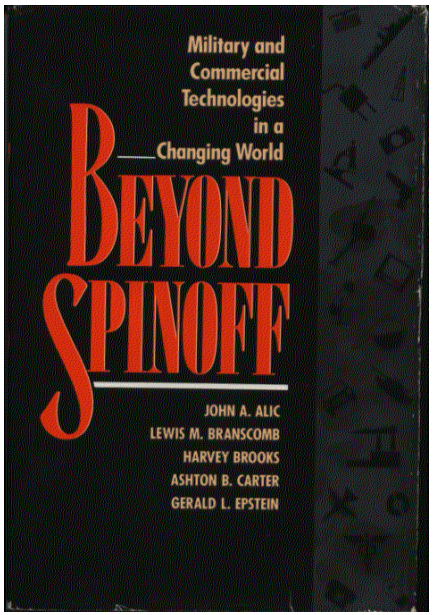
- Research
  - developing technology’s potential
- Familiarity
  - understanding technology’s potential
- Application
  - benefiting from technology’s potential
- Wide diversity of “dual-use” relationships

Dual-Use Technology Relationships (1)



- Direct Product Conversion
  - microwave oven
- Defense Procurement Pull
  - supercomputers; electronics
- Concurrent Development
  - jet engines; jet transports
- Shared Infrastructure
  - nuclear medicine; satellite communications

Dual-Use Technology Relationships (2)



- Development of tools and techniques
  - NASA Structural Analysis (NASTRAN)
- Support of generic research
  - lasers; artificial intelligence
- Reverse spinoff (“spin-on”)
  - CMOS semiconductors
- Forced diffusion via demonstration
  - Very High Speed Integrated Circuits (VHSIC)

Half Full or Half Empty?

- DoD official in R&D oversight role
  - DoD's engagement in biotech is "broad and deep" but driven by DoD requirements; pushing technology "in its broadest sense" into DoD "probably isn't going to work"
  - lots of interaction with industry in diverse areas going beyond medical applications to include foods; materials; bioremediation; etc.
- Former DoD program manager
  - "the interface is broken"

Barriers to Application of Biotech

- Biodefense “orphan product” barriers
- Security barriers
- Government procurement barriers
- New / unproven technology barriers
- Many of these are familiar (if not yet solved), but some are new or aggravated for biotech

Biodefense "Orphan Product" Barriers

- Highly uncertain threat
- Highly uncertain government market
- Government buyer unclear; commercial buyers unlikely
- FDA approval uncertainties
- Indemnification
- Market opportunities higher elsewhere

Government Procurement Barriers

- Intellectual property concerns
- Government accounting standards
- Vagaries of politics and budgets

Security Barriers

- Considerable overhead and expertise required to deal with classified information and materials
- Concerns regarding foreign nationals / alliances / ownership

New / Unproven Technology Barriers

- Technical risk -- real and perceived
- Difficulties in scale-up / production
  - "black art" in pharmaceuticals and vaccines
- Lack of standards / expertise with which to evaluate claims and dispel hype
  - particular problem given lack of biological expertise within DoD
  - less of a problem in medical applications
- No ability to mandate specific technologies
- Rigid and incompatible procedures
  - e.g., biodetection technology in USDA

Candidate Solutions

- DoD / USG-wide strategy for dealing w/ biotech sector
- An “In-Q-Tel” approach?
  - government-staked venture capital firm sensitive to government needs
- Mechanisms to increase relevant S&T expertise within government mission agencies
- Case-by-case approach